

Package leaflet: information for the user

Imodium[®]

PLUS

2mg/125mg tablets
Loperamide hydrochloride
Simeticone

Please read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Imodium Plus 2mg/125mg tablets carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after two days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Imodium Plus 2mg/125mg tablets are, and what they are used for.
2. Before you take Imodium Plus 2mg/125mg tablets.
3. How to take Imodium Plus 2mg/125mg tablets.
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1. What Imodium Plus 2mg/125mg tablets are, and what they are used for

The tablets are used to treat a short-lived attack of diarrhoea when it occurs with stomach cramps, bloating and wind.

The tablets contain two active ingredients:

- Loperamide hydrochloride, which helps reduce diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.
- Simeticone, which breaks up the gas bubbles in the bowel that causes cramps and bloating.

2. Before you take Imodium Plus 2mg/125mg tablets

Do not take Imodium Plus:

- In children less than 12 years old.
- If you are allergic (hypersensitive) to loperamide hydrochloride, simeticone or any of the other ingredients of the tablets (see section 6).
- If you have a high temperature (e.g. above 38° C) or blood in your stools.
- If you are having a flare up of an inflammatory bowel condition like ulcerative colitis.
- If you have severe diarrhoea after taking antibiotics.
- If you are constipated or your stomach appears swollen.

Take special care with Imodium Plus:

- Imodium Plus 2mg/125mg Tablets only treat the symptoms of diarrhoea. In some cases, the cause of your diarrhoea may require treatment, if symptoms persist or worsen, please contact your doctor.
- If you have severe diarrhoea your body loses more fluid, sugars and salts than normal. You will need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about special powders which replace the sugars and salts.
- If you have AIDS and your stomach becomes swollen, stop taking the tablets immediately and contact your doctor.
- If you have liver disease, check with your doctor before using the tablets. Some of the side effects might be more troublesome.

Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines including:

- quinidine (used to treat abnormal heart rhythms or malaria)
- itraconazole or ketoconazole (antifungal medicines)
- gemfibrozil (used to treat high cholesterol)
- ritonavir (used to treat HIV infection and AIDS)
- desmopressin (used to control thirst and urine production in patients with diabetic insipidus)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription because Imodium Plus 2mg/125mg Tablets may interact with them.

Pregnancy and breast feeding: Pregnancy: If you are pregnant or if you think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine. Breast feeding: Do not take Imodium Plus if you are breast feeding. Small amounts of the medicine could end up in your milk.

Driving and using machines: This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.

3. How to take Imodium Plus 2mg/125mg tablets

Unless your doctor has told you otherwise, follow these instructions:

- Swallow the correct number of caplets whole with a drink of water
- For oral use only
- Do not use more than the stated dose

Adults over 18 years old: Swallow two tablets initially, followed by one tablet after every loose stool (bowel movement). Do not take more than four tablets in a day. If you are no better after two days, stop taking the tablets and contact your doctor.

Adolescents aged 12 to 18 years old: Swallow one tablet initially, followed by one tablet after every loose stool (bowel movement). Do not take more than four tablets in a day. If you are no better after two days, stop taking the tablets and contact your doctor.

Do not give the tablets to children less than 12 years old.

If you take more Imodium Plus than you should: Too many tablets may make you feel drowsy, or make it difficult to think clearly or carry out normal activities. Your muscles may feel stiff or you may experience breathing difficulties. You may have a dry mouth or the pupils of your eyes may become small. You may have stomach pain, feel sick or vomit, be constipated or have difficulty passing water.

If you have taken too many tablets, contact a doctor or hospital for advice.

If you forget to take Imodium Plus: Take one tablet after the next loose stool (bowel movement). Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Imodium Plus can cause side effects, although not everybody gets them.

If you experience any of the following stop using the medicine and seek immediate medical help:

Allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.

If you experience any of the following, stop using the medicine and talk to your doctor:

- Difficulties passing water
- Severe abdominal pain, abdominal bulging or swelling or fever which may be due to a blocked or enlarged bowel
- Severe constipation

Other effects which may occur include:

Common side effects (less than 1 in 10 but more than 1 in 100 people get these):

- Headache
- Feeling sick
- A change in the way some things taste

Uncommon side effects (less than 1 in 100 but more than 1 in 1000 people get these):

- Drowsiness
- Dizziness
- Weakness
- Constipation
- Vomiting
- Indigestion
- Wind
- Dry mouth
- Rash

Rare side effects (less than 1 in 1000 but more than 1 in 10,000 people get these):

- Loss of consciousness or decreased consciousness
- Excessive contraction of the pupil of the eye
- Skin rash, which may lead to severe blistering and peeling of the skin
- Hives
- Itching
- Tiredness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Imodium Plus 2mg/125mg tablets

Keep out of the reach and sight of children. Do not use the tablets after the expiry date on the blister and box. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Imodium Plus 2mg/125mg tablets contains:

The active substances are: loperamide hydrochloride (2 mg per tablet) and simeticone (measured as 125 mg dimeticone per tablet).

The other ingredients are: calcium hydrogen phosphate anhydrous, microcrystalline cellulose, acesulfame potassium, artificial vanilla flavour (includes propylene glycol, maltodextrin and benzyl alcohol), sodium starch glycolate type A and stearic acid.

What Imodium Plus 2mg/125mg tablets look like and contents of the pack:

The tablets are white capsule shaped tablets marked with a line between "2" and "125" on one side and "IMO" on the other side.

Each pack contains 6, 8, 10, 12, 15, 16, 18 or 20 tablets in blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

McNeil Healthcare (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland.

Manufacturer:

Janssen-Cilag SpA, Via C. Janssen, Borgo San Michele, Latina, Italy.

This medicinal product is authorised in other countries under the following names:

Belgium: Imodium Duo 2mg/125mg tabletten	Netherlands: Imodium Duo 2mg/125mg tabletten
Denmark: Imodium Plus	Norway: Imodium Comp
Finland: Imodium Plus tabletit	Portugal: Imodium Plus
France: Imodiumduo Comprime	Spain: Imodium Duo 2mg/125mg comprimidos
Germany: Imodium akut N Duo	Sweden: Imodium Plus 2mg/125mg tablett
UK: Imodium Plus caplets	
Luxembourg: Imodium Duo 2mg/125mg tabletten	

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